

Message

**From:** Kausch, Jeannine [Kausch.Jeannine@epa.gov]  
**Sent:** 2/15/2017 10:43:11 PM  
**To:** Tapken, Wiebke [Tapken.Wiebke@epa.gov]  
**CC:** Djurickovic, Milutin [Djurickovic.Milutin@epa.gov]; Wozniak, Chris [wozniak.chris@epa.gov]; Borges, Shannon [Borges.Shannon@epa.gov]; Kough, John [Kough.John@epa.gov]; Jones, Russell [Jones.Russell@epa.gov]; Eiden, Catherine [Eiden.Catherine@epa.gov]; Carlisle, Sharon [Carlisle.Sharon@epa.gov]  
**Subject:** New Assignment - Extension and Amendment to 89668-EUP-3 (Wolbachia pipientis, wAlbB strain in Aedes aegypti)  
**Attachments:** Notice of Receipt for Wolbachia EUP Amendment and Extension - Draft

Hi Wiebke,

I am assigning you to be the regulatory lead for one new action (experimental use permit extension and amendment; 89668-EUP-3). In a cursory reading of the application materials, the applicant (MosquitoMate, Inc.) appears to be requesting to incorporate a new manufacturing process (by Verily Life Sciences, Inc.), add new experimental sites (Miami-Dade County, Florida; Harris County, Texas; and Lee County, Florida), and extend testing through December 2018.

Active Ingredient	Action Code	RAL	Hlth/ID SR*	Eco SR*	Other SR*	IRM SR*	Co #	Prd	EUP/PA	PRIA Start	Phase II Due	Phase IV Due
Wolbachia pipientis, wAlbB Strain	B621	Wiebke	MD	MD	CW	X	89668	3	EUP	2/15/2017	5/16/2017	6/17/2017

Some items to note with this application are as follows:

- (1) Your science team is Milutin (product characterization, human health, & ecological) and Chris W. (Section G).
- (2) This application came in as paper only. Thus, only newly submitted studies are available in Documentum. All other materials (administrative documents, e.g., Section G description and label) are in the jacket that I transferred to you yesterday.
- (3) Please work with your science team to conduct and complete the preliminary technical screening NLT Tuesday, May 2, 2017 (2 weeks before the Phase II due date). Note: When I was looking through the application materials, I noticed that it was not clear whether MosquitoMate, Inc. wants to continue to do testing in Orange County, CA and Monroe County, FL in 2017 and 2018. This needs to be clarified with MosquitoMate, Inc. and included in the Section G description (if testing is to be continued in the two aforementioned counties).
- (4) You may have to do a Notice of Receipt for this action, but I sent Mike M. an draft argument against doing this last week (see attached). Mike was supposed to send something upstairs this week, so please check in with him regarding deliberation on this particular part of the action. If OPP senior management wants to do a Notice of Receipt, you need to know this in order to get this going ASAP.
- (5) Management may want this action expedited, but this directive will need to come from them.

In addition to your science team, I am also cc'ing MPB's senior scientists, the individuals that will be RAPLs once reorganization occurs, and ShaRon. Please let me know if you have any questions.

Thanks!  
Jeannine



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